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10/634,845	08/06/2003	Hiraku Murayama	011350-316	6514
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EXAMINER				
HOEKSTRA, JEFFREY GERDEN				
ART UNIT		PAPER NUMBER		
3736				
NOTIFICATION DATE		DELIVERY MODE		
06/05/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary

Application No.

10/634,845

Applicant(s)

MURAYAMA ET AL.

Examiner

JEFFREY G. HOEKSTRA

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,8-15,18-31,36 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,8-15,18-31,36 and 39-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 03/18/2008.
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 03/18/2008, amended claim(s) 1, 3, 11, 12, 21, 22, and 29, cancelled claim(s) 7, 17, 37, and 38, and new claim(s) 39-42 is/are acknowledged. The current rejections of the claim(s) 1, 3, 8-15, 18-31, and 36 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

2. Claims 39 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. The Examiner reiterates and emphasizes Applicant's Election of Species II drawn to Figure 3 on 11/03/05.

3. Claims 39 and 40 are withdrawn as being drawn to nonelected Figure 1 described in the instant Specification in paragraph 84.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

5. The information disclosure statement(s) (IDS) submitted on 03/18/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97

and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Objections

6. Claims 41 and 42 are objected to because of the following informalities: the positive recitation of "said cover layer is made from a reaction-curing type" should apparently read "said cover layer is made from a reaction-curing type of the resin material". Appropriate correction is required.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 3, 8-14, 18-24, 26-31, 36 and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino et al. (US 6,001,068, hereinafter Uchino) in view of Richardson et al. (US 6,494,847 B1, hereinafter Richardson).

9. For claims 1, 3, 9, 10, 26, and 36, Uchino teaches a guidewire (as best seen in Figures 1 and 3), comprising:

- a wire member (1) comprising a first distal wire (A) having a proximal end face (the right end face of wire A) butt resistance welded (column 7 line 60 – column 8 line 24) to a second proximal wire (B) having a distal end face (the left end face of wire B) to create a welded portion, wherein said first distal wire's proximal end face does not axially overlap said second proximal wire's distal end face (as best seen in Figures 3(3));

- a cover layer (12) covering the welded portion and provided on an outer periphery of the wire member, said cover layer uniformly covering said welded portion (as best seen in Figure 3(4)), wherein said cover layer can be made of a metal with an elastic modulus that is less than that of said first wire (column 3 line 37 – column 4 line 65 and column 11 line 11 – column 14 line 67) or a resin comprising silicon resin (column 6 lines 19-65 and column 11 line 11 – column 14 line 67), and wherein said cover layer is made of a resin material that reduces friction (column 4 lines 34-41, column 6 lines 62-63, and column 10 lines 20-32); and
 - a distal-side cover layer (113) disposed distally from said cover layer (as best seen in Figure 1), made from a different material (and column 11 line 11 – column 14 line 67), and not overlapping said cover layer (as best seen in Figure 1),
 - wherein the distal-side cover layer is capable of being formed in a manner such that the wire member is heated at a time of covering the wire member with the distal-side cover layer, and
 - wherein the cover layer is capable of being formed such that the wire member is not heated at a time of covering the wire member with the cover layer.
10. For claims 8-10, 12-13, 18-20, 22-23, and 27-28, Uchino teaches said cover layer and said distal-side cover layer being hydrophilic and reducing friction (column 12 lines 47-56).
11. For claims 14, 24, 30 and 31, Uchino teaches a composite guidewire comprising different wire materials including: said distal wire being a superelastic alloy wires and

said proximal wire being stainless steel (column 3 line 37 – column 4 line 65 and column 11 line 11 – column 14 line 67).

12. For claims 41 and 42, Uchino teaches a composite guidewire wherein the cover layer is a composite material that is capable of being performed at room temperature (column 4 lines 34-41, column 6 lines 62-63, and column 10 lines 20-32).

13. Thus for claims 1, 3, 8-10, 12-14, 18-20, 22-24, 26-28, 30-31, 36, and 41-42, Uchino teaches the claimed invention, as set forth above, except for expressly disclosing the guidewire having (a) a proximal-side cover layer disposed on a proximal side from the cover layer without an axial gap or overlap between the cover layer and the proximal-side cover layer or (b) the distal-side cover layer disposed on a distal side from said cover layer without an axial gap between the cover layer and the distal-side cover layer. Richardson teaches a guidewire (50) having (a) a proximal-side cover layer (62) disposed on a proximal side from a cover layer (66) without an axial gap or overlap between the cover layer and the proximal-side cover layer (as best seen in Figure 7) (column 4 lines 33-60) and (b) a distal-side cover layer (56) disposed on a distal side from said cover layer without an axial gap or overlap between the cover layer and the distal-side cover layer (as best seen in Figure 7) (column 4 lines 33-60). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Uchino and Richardson. The only difference is the combination of the component parts into a single

device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Uchino with the components as taught by Richardson to achieve the predictable results of configuring the mechanical properties of a guidewire to traverse tortuous vasculature.

14. For claims 11, 21, and 29, Uchino in view of Richardson teaches the claimed invention but does not disclose expressly the thickness of the cover layer and distal-side cover layer being 1 micron. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the guidewire as taught by Uchino in view of Richardson with the thickness of the cover layer and distal-side cover layer being 1 micron, because Applicant has not disclosed that the thickness of the cover layer and distal-side cover layer being 1 micron provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the thickness of the metallic layer (column 12 lines 24-25) as taught by Uchino in view of Richardson, because it provides for connecting unlike materials when configuring a guidewire with varying mechanical properties and since it appears to be an arbitrary design consideration which fails to patentably distinguish over Uchino in view of Richardson. Therefore, it would have been an obvious matter of design choice to modify Uchino et al to obtain the invention as specified in the claim(s).

15. Claims 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchino in view of Richardson and in further view of Reynolds et al (US 2003/0069521 A1, hereinafter Reynolds). Uchino in view of Richardson teaches the

claimed guidewire, as set forth above, except for expressly disclosing the use of Co-Ni-Cr based alloy wire. Reynolds et al teaches the use of cobalt-based alloys in guidewire construction (paragraph 33). All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. All of the component parts are known in Uchino in view of Richardson and Reynolds. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Uchino in view of Richardson with the components as taught by Reynolds to achieve the predictable results of configuring the mechanical properties of a guidewire to traverse tortuous vasculature.

Response to Arguments

16. Applicant's arguments with respect to claims 41-42 have been considered but are moot in view of the new ground(s) of rejection.

17. Applicant's arguments filed 03/18/2008 have been fully considered but they are not persuasive. Applicant argues the 103(a) rejection of the claims under Uchino in view of Richardson, specifically arguing (a) the cover layer of Uchino is not made of a resin material that reduces friction, (b) the cover layer of Uchino is not made of a silicone resin, (c) the cover layer of Uchino does not cover a welded portion, and (d) the cover layer of Uchino is not formed such that the wire member is not heated at a time of

covering the wire member with the cover layer. The Examiner disagrees, maintains the rejection as set forth and reiterated above, and in response notes the following:

18. In response to Applicant's arguments (a), (b), and (c), that the cover layer of Uchino is not made of a resin material that reduces friction, is not made of a silicone resin, and does not cover a welded portion. The Examiner notes Uchino expressly discloses that the cover layer is made of a resin material that reduces friction, is made of a silicone resin, and does cover a welded portion (column 4 lines 34-41, column 6 lines 62-63, and column 10 lines 20-32) (as best seen in Figures 3.1-3.5).

19. Moreover in response to Applicant's arguments (a), (b), and (c), the Examiner notes Uchino states at the cited passages the following:

- "There is no special condition for the material for the tubular connector 12," (i.e. the cover layer) "and various plastics and metals can be used as for the first wire A and the second wire B" (column 4 lines 34-41);
- "fluororesin such as polytetrafluoroethylene or silicone, for example" (column 6 lines 62-63); and
- "Although the guide wire of this invention is described above using embodiments shown in Figures, this invention is not limited to these embodiments. For example, the first wire A and the second wire B constituting the wire main body may be either solid or hollow, and may be formed of various resin materials such as polyimide, polyester, polyolefin (polypropylene, polyethylene, etc.), fluororesin, and polyurethane, in addition to metals such as aforementioned super elastic alloy, piano wire, stainless steel, and tungsten. The wire main body may also be formed of wires

which are made of two or more layers of different materials or properties" (column 10 lines 20-32).

20. In response to Applicant's argument (d) that the cover layer of Uchino is not formed such that the wire member is not heated at a time of covering the wire member with the cover layer, the Examiner notes that the cover layer as disclosed by Uchino and cited above is capable of being formed such that the wire member is not heated at a time of covering the wire member with the cover layer and capable of being performed at room temperature. The Examiner notes that the claim limitations upon which Applicant are relying (i.e. "the cover layer formed such that the wire member is not heated at a time of covering the wire member with the cover layer" and "the cover layer formed at room temperature) appear to be product-by-process limitations as they are positively reciting limitations of the product (i.e. the guidewire) by the process by which it is made (i.e. "the cover layer formed such that the wire member is not heated at a time of covering the wire member with the cover layer" and "the cover layer formed at room temperature). Applicant is reminded that product-by-process claims are not limited to the manipulations of the recited steps, only to the structure implied by the steps (see MPEP 2112.01 and 2113). In addition, attorney's arguments are not the kind of factual evidence that is required to rebut a prima facie case of either anticipation or obviousness (see MPEP 2145).

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736